THE REAL DEAL

INNOVATION IN HEALTHCARE
HAAS SCHOOL OF BUSINESS

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Main Entry: **due diligence** Function: *noun* Date: 1903

1) The care that a reasonable person exercises under the circumstances to avoid harm to other persons or their property

2) Research and analysis of a company or organization done in preparation for a business transaction (such as a corporate merger or purchase of securities)
Due Diligence, According to Me

Due Diligence is used to evaluate risk and opportunity:

- **Is it a good idea?**
  - Confirm whether what you think you know is true
  - Learn new things, positive or negative
  - Find out if there is a better idea out there

- **Is it likely to be a good relationship?**
  - Is this the best team money can buy?
  - Do I want to spend the next 7-10 years with

- **Is it a good investment?**
  - Does this really fit my investment model?
  - Can this deliver the returns that I need?
  - What is the downside scenario

- **What are the risks?**
What’s Fair Game?

- Everything!
- Nothing is sacred, but be respectful of management’s time
- Be sure to talk with:
  - All management team members and board members
  - Rank and file staff
  - If you can find them, former executives
  - Key company advisors (lawyers, accountants, etc.)
  - Partners of the company
  - Customers: current, former and prospective
  - Customer influencers, such as clinicians, industry experts, associations, etc.
  - Competitors, but be ethically appropriate
  - FDA (if appropriate), CMS, etc., (but be careful not to compromise the company)
  - Market analysts and investment bankers
  - Investors in past rounds
When Do You Perform Due Diligence?

- Before the term sheet
- After the term sheet
- Up until the moment of closing
- When you think about participating in the next round

"The moment I saw this, my soul cried out that it could triple in value."
The Due Diligence Team

- You’re the leader: it’s your job to lay out the plan
- Your partners in the firm
  - understand their issues/objections so you can address them before the Investment Committee vote
- Expert team
  - Lawyers, corporate and IP
  - Accountants
  - Technical experts (clinical, engineering, other)
  - Private investigator (background checks)
Due Diligence: A 12-Step Program

1. Validity of Idea
2. Quality of Team
3. Operational Fundamentals
4. Sales & Marketing Requirements and Plan
5. Regulatory Environment
6. Reimbursement Environment
7. Financials
8. Legal
9. Competitive Landscape
10. Corporate Structure
11. Capital Structure
12. Exit Scenarios & Returns Analysis

“I was wondering when you’d notice there’s lots more steps.”
1. Validity of the Idea

- Is there really a market?
  - Market size
    - Calculated based on the potential universe of buyers times the price you can charge, for example:
      - Product: angioplasty catheter for complex lesions
      - 1 million angioplasties in the U.S. each year
      - But really: 350,000 angioplasties for complex lesions
      - Product can be sold for $850
      - Market size = $350,000 * $850 = $297,500,000 (not $850,000,000)

- Who adopts and why?
  - Characteristics of an ideal customer
  - What are incentives to adopt/purchase?

- What are barriers to adoption?
  - Inertia
  - Cost
  - Hassle factor/switching cost
  - Competitive option
  - Market hard to penetrate

**Questions you are trying to answer:**

"Business is lousy. Maybe I should have done more market research first."
1. Validity of the Idea, continued

- Is the clinical/scientific/technical basis valid?
  - Does the product do what they say it does?
    - Can one watch the product in action?
    - Is there evidence of the claimed result?
      - If not, what will it take to produce evidence?
    - Does the development of the product require a scientific/technical breakthrough that has not yet happened?
    - If no evidence and no working model, what is a good proxy? In other words, how much of a leap of faith are you willing to take?
  - Is there a paradigm shift on the horizon that would render the idea moot?
    - For example: Someone comes to you with an amazing new cardiac surgery product to perform better Coronary Artery Bypass Surgery…..
      - It’s faster, it’s cheaper, it’s safer
      - BUT, it’s a declining market as catheter-based procedures have replaced a vast proportion of CABG surgeries
      - Is it a good investment?
2. Quality of the Team

Questions you are trying to answer:

- Is the team effective? Is there a time they will cease to be effective?
  - Have they met plan in the past?
  - How is the corporate culture?
  - What do employees, board and customers say?

- What skills do they lack?
  - Can that void be filled out by another team member?

- Are they who they say they are?
  - References
  - Background checks
  - How are the books?
  - Red flags: bankruptcies, lawsuits, criminal record, etc.

- Does management compensation make sense?

- Do you like spending time with them?
  - Are their goals consistent with yours?
  - Is there a culture and personality fit?

Would you have invested in these people?
3. Operational Fundamentals

Questions you are trying to answer:

- Manufacturing and/or service delivery issues
  - Do things run smoothly?
  - Capacity
  - Scalability
  - Supply chain management and risks
  - Plant upgrade and capex requirements
- Quality and customer satisfaction/complaints
- COGS
  - What is it and what can it be at high volume?
  - In-sourcing vs. outsourcing
- Technology infrastructure
- Human Resources
  - Are they properly staffed for now and for growth?
  - What are challenges to hiring/retaining optimal team?
4. Sales & Marketing Plan

Questions you are trying to answer:

- Launch requirements and plans
  - When?
  - Where?
  - How? What is a reasonable sales ramp?

- Sales model
  - Direct
  - Distribution

- Sales force hiring plan
  - Profile of ideal salesperson
  - Compensation and commission model
  - Productivity metrics
  - Speed of hire vs. cost of hire
  - E.g., a fully loaded sales person may cost $400K but it takes over 12 months to get them to full productivity/breakeven—when do you hire?

- What are the competitors doing and how does it compare?
5. Regulatory Environment

Questions you are trying to answer:

- What regulations and regulatory bodies govern company behavior and influence success?
  - FDA and foreign regulatory bodies
    - Cost and difficulty of clinical trial (PMA vs. 510K)
  - Are there financial regulations that govern the industry?
  - Are there provider regulations?
  - Anything working for you, regulatory-wise?

- Regulatory compliance up to snuff?
  - What is cost of ongoing compliance?
  - Is the company able to meet regulatory requirements on an ongoing basis?

"These new regulations will fundamentally change the way we get around them."
6. Reimbursement Environment

Questions you are trying to answer:

- Who is going to pay for this?
  - How much?
  - Under what circumstances?

- What is the path to an AMA reimbursement code, if needed?
  - What is process? Timeline?
  - Who stands to gain? Lose?

  For example: Point-of-care diagnostic tests

  - Winners: Physician (revenue opportunity), Patients (convenience), Payers? (early diagnosis leads to early less costly treatment)
  - Losers: Clinical labs (revenue loss), Payers? (more tests done—more cost)
  - Who influences decision about reimbursement codes?

Aside from team and idea itself, reimbursement is one of the largest risks in healthcare deals.
7. Financials

Questions you are trying to answer:

- Financial Model
  - Are assumptions driving the model realistic? What are the barriers to success?
    - You need a bottoms-up model, not top down
    - Question everything
      - Revenue assumptions
      - Cost assumptions
      - Salary assumptions
      - Time assumptions
      - Cash flow vs. GAAP Model
  - Have past results validated future assumptions?
  - Is the pricing model rational? What do customers say?
  - Are cash flow assumptions reasonable? How much cash do they really need to breakeven?
    - Answer: more than they think, so how much?
Questions you are trying to answer:

- Financial Reporting/Accounting
  - Do they have appropriate financial controls?
    - Scrutinize the reporting and oversight function
    - Who authorizes spending?
  - Is revenue recognition appropriate?
  - How are the collections?
  - Any evidence of fraud?
    - Always always interview the accountants
    - Hire your own accountants to review the books

Look around: is their furniture better than their business plan?
8. Legal

Questions you are trying to answer:

- **Intellectual Property**
  - Do they have freedom to operate?
    - Would their lawyer put it in writing?
  - Who can they block?
  - How easy is it to work around?
  - Does it really matter?

- **Any legal issues standing in the way of investment success?**
  - Lawsuits? If so why? How risky?
  - Any impending legislation that can impact the business?
    - For example, the health reform bill....
Questions you are trying to answer:

- Who else is tackling this problem and how do they compare?
  - When they tell you there is no real competition, they are kidding you or themselves
  - Inertia is a competitor

- What does it take to be the market leader?
  - Who influences your path to that role?
    - KOL vs. rank and file strategy
  - What does it cost to compete with the “big guys”?
    - For instance, few new health insurance companies are funded due to the expense of creating them and the brand recognition of the current players
    - For instance, few new imaging companies break through as stand-alone because cost of competing with Siemens, Toshiba, GE is too high

- Who will try to stop you and what are their odds?
10. Corporate Structure

Questions you are trying to answer:

- How is the company incorporated?
  - This can impact investment returns and risks
    - Good states vs. bad states
    - Tax treatment
  - If you need to restructure, the time is when your money goes in

- Is the company in good standing?
  - Sloppy structuring/documentation is evidence of sloppy management

- Is the Board of Directors functional?
  - Who should be on it? Stay on it? Leave?
  - Who should be added to improve effectiveness?
11. Capital Structure

Questions you are trying to answer:

- How much money has gone in and how was it used?
  - How much value creation versus wasted cash?
- Who invested previously
  - Why did they invest? Has the investment lived up to expectations?
  - Will they invest in this round? Why or why not?
  - How much reserve are they holding for the company?
  - How is the stability of existing investors’ funds?
- Does capital structure impede investment success?
  - Alignment of management incentives
    - How much does management own?
    - How buried are they in the capital structure?
  - Who controls the vote? Who can stand in the way of exit, future rounds?
  - Any prior investment terms that stand in the way of your returns?
    - E.g., prior participating preferred may suck up too much value
12. Exit Scenarios & Returns Analysis

Questions you are trying to answer:

- What is the right valuation?
  - The wrong valuation can turn a good deal bad
- Can you make the return you need at the valuation of the deal?
  - What is the range of exit values?
  - In a downside scenario, what is the asset value, if any?
- Is this company a candidate to go public?
  - Is there a public market?
  - Is the product platform broad enough?
  - How fast can it get big enough?
- Who could buy this company and why would they?
  - What is going on internally with the buyers?
- What is the exit timeline?
  - What is the CEO’s timeline?
  - What is the other investors’ timeline?
  - How does this match with your timeline?
Some of My Favorite Due Diligence Questions

- **For the CEO**
  - What is the biggest mistake you made so far? What did you do about it?
  - Would you rather be famous for your accomplishments or wealthy and unknown?
  - What is your specific definition of personal financial success?
  - When will you need to be replaced and how are you going to handle it when I tell you your time has come?

- **For the team**
  - Who on the team is indispensable?
  - Who is the weakest link?
  - What does the CEO really not know about what is going on day to day?

- **For customers**
  - Who/what at the company has impressed you? Disappointed you?
  - What is the most pressing problem you have to solve? How does the importance of this thing rate by comparison?
  - Specifically, what would it take for you to buy/use this product/service today?
  - Who is their most obvious competitor in your mind?
  - What is the coolest new product/service you have seen this year?
Due Diligence is Done—Now What?

- Move Forward To Closing
- Restructure The Deal
- Defer/Delay
- Run Away

The most common outcome
Final Thoughts

- It is critical to keep an open mind and not use the process to validate your pre-existing beliefs
  - Don’t drink your own Kool-Aid

- Management’s cooperation tells you a lot about their willingness to work with you later
  - Don’t invest with people you can’t stand to be with

- Don’t take the company’s assertions at face value

- If you get a bad feeling in your gut, listen to it

- If you do invest, share what you learned with the company